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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,766	11/12/2004	Pascal Bigey	029440.00001	3543
4372	7590	01/24/2008		
ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER SHIN, DANA H	
			ART UNIT	PAPER NUMBER
			1635	
			NOTIFICATION DATE	DELIVERY MODE
			01/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

## Office Action Summary

**Application No.**

10/506,766

**Applicant(s)**

BIGEY ET AL.

**Examiner**

Dana Shin

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-16, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-16, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

This Office action is in response to the communications filed on and December 12, 2007.

Currently, claims 1-3, 7-16, and 29-30 are under examination on the merits.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **Maintained Rejections**

#### ***Claim Rejections - 35 USC § 103***

Claims 1-3, 7-16, and 29-30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Szyf et al. in view of Monia et al. and Deeley et al. for the reasons of record as set forth in the Office action mailed on June 13, 2007 and for the reasons stated below.

Applicant's arguments filed on December 12, 2007 have been fully considered but they are not persuasive. Applicant argues that "none of these three references suggest their combination" and that the claimed invention is only possible "upon knowing the invention". In

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so arguing, applicant addresses the teachings of the three references individually. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, a combination product of an antisense oligonucleotide and a chemotherapeutic agent was known to be used as anticancer agent as taught by Monia et al. Although Monia et al. did not teach an anti-MBD2 antisense oligonucleotide, Szyf et al. expressly taught that an anti-MBD2 antisense oligonucleotide is an anticancer agent. As noted in the previous Office action, it has been recognized as *prima facie* obvious to combine two agents that are useful for the same purpose, in order to form a combination product that is used for the very same purpose. See *In re Kerkhoven*. In the instant case, the combination product comprising an anticancer agent MBD2 antisense oligonucleotide and another anticancer agent bleomycin is claimed to be used as an anticancer agent. Given the direct teaching of Monia et al. that such combination products comprising an antisense oligonucleotide and an anticancer agent is an effective anticancer drug, it is unclear how applicant views that the references contain "general teachings fall short of leading the skilled artisan in a direct path toward the claimed invention as is required to support a *prima facie* case of obviousness."

Applicant further argues that the synergistic effect of the combination product comprising an antisense oligonucleotide and bleomycin was an unexpected result. It appears questionable

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why the observed synergistic effect was an unexpected result since the anti-MBD2 antisense oligonucleotide was taught to be an anticancer agent by Szyf et al. and since bleomycin is a known chemotherapeutic anticancer agent and therefore it would logically flow that combining the two anticancer agent would necessarily produce additive or synergistic effects. Further, applicant has not provided any factual, objective evidence showing that the alleged synergistic effect of the claimed combination product is indeed unexpected.

Applicant further contends that the nature of the art of the invention is highly unpredictable and therefore there would have not been a reasonable expectation of success. The claimed invention is drawn to a combination product comprising an antisense oligonucleotide and bleomycin. Making such combination product was known as taught by Monia et al. and therefore the technique of making such combination product, either by simultaneous or sequential administration, was available and known in the art. Since the knowledge and skills required to make the claimed combination product were within the technical grasp of one of ordinary skill in the art at the time of the invention, one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed product.

Since applicant's arguments have failed to address why the claimed invention taken as a whole would have been unobvious over the combined teachings of the prior art, this rejection is maintained.

### ***Conclusion***

No claim is allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin  
Examiner  
Art Unit 1635

/J. E. Angell/  
Primary Examiner